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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mary J. Champion

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

09/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,803	Applicant(s) CHAMPION, MARY J.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,35,36,38,41,44,45,55,57-59,61-65,68 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,38,41,44,45,55,57-59,61-65, 68, 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 06/26/2009.

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68, 70 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0176904 ('904) for Patterson in view of any of JP 2002119529 ('529) for Kobayashi or US 6,224,899 ('899) for Misumi et al. and further in view of the article "Thermoregulatory physiology of menopausal hot flashes: a review" by Kroneberg et al.

US '904 teaches cooling therapy for women experiencing hot flashes wherein the cooling therapy is provided as bandage comprising strips of cooling gelatinous material, adhesive to fix the gelatinous material to the skin on one side and cotton fabric on the

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other side (abstract; paragraphs 0010, 0012, claim 4). Cotton is used by applicant as gas permeable substrate at page 13, lines 15-16 of the present specification. The strips can be applied under clothes across the chest (paragraph 0012). The term across, according to the "WEBSTER'S II Dictionary" means: "from one side to the other".

Therefore, the disclosure of the reference encompasses the application of the strip or bandage on the back of the user in order to be under the clothes because the reference is concerned with problem of embarrassing the women using the cooling strips (abstract, paragraph 0008). The reference further teaches that strip is provided in pouch, which reads on the package (paragraph 0012). The reference does not teach the presence of any active agent in the strip. The instruction does not impart patentability of the claims. The claims are obvious by the reference since it has been held by the court that when the only difference between the prior art product and the claim is the "written instruction to the consumer", the claim is obvious over the art. See *In re Ngai 03-1524*.

Although US '904 suggested application of the cooling strip across the chest, however, the reference does not explicitly teach that the back is the site of origin of the hot flashes as recited by claims 33, 55 and 61.

US '904 does not describe the gel as water containing gel comprising polyacrylic acid component as claimed by claims 35, 36, 38, 55, 57-59, 62-65, 67 and 68.

JP '529 teaches cooling patch for cooling the affected regions continuously in early stage and can maintain a cooldown delay, said patch comprises water permeable

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film covered with hydrous paste of polyacrylic acid, i.e. containing water (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-61). The cooling patch can be applied locally to the area of discomfort without limitation to the body part, such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso, i.e. trunk (page 1313, right column).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling sheet/strip applied across the chest to treat hot flashes comprising gelatinous material located between skin adhesive and cotton fabric layer as taught by US '904, and apply the strip to the origin of the hot flashes and make the strip of hydrous material comprising polyacrylic acid as taught by any of JP '529 and US '899. One would have been motivated to do so because JP '529 teaches that such a cooling patch can be applied to the affected area that in need of cooling and hydrous polyacrylic acid can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay. Further, one would have been motivated to do so because US '899 teaches that cooling sheet can be applied locally to the area of discomfort and polyacrylic acid cooling gel is stable and is

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excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue. One would have reasonably expected treating hot flashes using cooling strip or sheet applied across the chest comprising polyacrylic acid gelatinous material located between skin adhesive and cotton fabric layer wherein the strip or sheet is applied at the site of origin of the discomfort, in this case is the hot flash, and is able to maintain the cooling effect and preserve the coolness to treat hot flashes successfully and effectively. Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to apply the cooling sheet taught by the combination of US '904 with any of JP '529 or US '899 to the back of the women as taught by Kroneberg et al. One would have been motivated to do so because Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso. One would have reasonably expected treating hot flashes by applying cooling sheet to the upper back which is the primary site of onset of the hot flashes.

Response to Arguments

3. Applicant's arguments filed 06/26/2009 have been fully considered but they are not persuasive.

Applicant argues that Patterson discloses a self-adhering cotton fabric cold strip that is worn as a wrist band or an ankle band and has an envelope defining a sealed cold strip volume. Patterson discloses that a cooling gelatinous material is positioned on the cold strip volume and that a bandage sheet is fixed to the envelope and the

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bandage sheet defines a bandage adhesive for temporary adhesion of the cold strip to the skin surface. The Examiner cites paragraph 0012 of Patterson which discloses that the strip is placed around the wrist or ankle or under clothes across the chest. The Examiner cites Webster's II Dictionary to refer to the term "across" as meaning from one side to the other". The Examiner concludes that the disclosure of Patterson encompasses the application of the strip on the back of the user.

In response to this argument, it is argued that applicant herself admits that Patterson teaches cold strip having adhesive for attaching the cooling strip to the skin of the user, and further admits that the reference teaches application of the cooling gelatinous strip across the chest, which encompasses any point across or around the chest cage from one side to the other including front and back of the chest all around. Patterson desired to apply the patch to invisible area of the body, as applicant did. It has been held by the court that aesthetic changes that have no mechanical function cannot be relied upon to patentability distinguish the claimed invention from the prior art. See *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947). The result achieved by Patterson is the treatment hot flashes as applicant desired. The site of application of the patch in the upper back or between the clavicles is suggested and taught by Patterson by teaching across the chest. In any event, the site of application of the cooling strip does not impart patentability to the claimed method because the patch will work the same way effectively and equally regardless of the site of its application as evident by the teaching of the reference wherein the hot flashes were treated. The burden is on applicant to

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show unexpected effect on treating hot flashes by the claimed patch when applied to upper back compared to any other area across the chest as taught by Patterson.

Applicant argues that Patterson does not disclose, teach or suggest providing a woman experiencing a hot flash associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device on a skin region at a location on the upper back of the woman to thereby treat the hot flash associated with menopause where the location on the upper back of the woman is the site of origin of the hot flash. The Examiner contends that Patterson's use of the phrase "across her chest" means on a skin region at a location on a upper back of a woman. In the context of the Patterson disclosure, it is clear that Patterson discloses placing the strip around the woman's wrist or around her ankle or under her clothes across her chest.

In response to this argument, it is argued that Patterson clearly teaches packaging of the cooling strip, and its use after its removal from the package, it will not be applied in its package to the skin. The site of application of the cooling strip is suggested by Patterson, as applicant herself admits. The reference suggests across the chest, which either any point across the front or back of the chest, or the strip goes all around the whole chest under cloth to be invisible, and in this case it will be applied to area encompassing the back over the vertebrae, as applicant did. Chest is not only front of the chest, it is front and back of the chest. Regarding the instruction, it does not impart patentability of the claims. The claims are obvious by the reference since it has

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been held by the court that when the only difference between the prior art product and the claim is the "written instruction to the consumer", the claim is obvious over the art. See *In re Ngai 03-1524*. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Applicant argues that Patterson provides no suggestion whatsoever that the strip is to be placed at a location on a skin region of the upper back of the woman. Since the surface of a woman's chest is directly opposite from a skin region on the woman's upper back, Patterson teaches clearly, directly and away from the present invention. Any rational person, let alone one of ordinary skill in the art understands that, in the context of Patterson and the present claims, the terms "chest" and "a skin region on an upper back of a woman" are entirely different and distinct, one from the other.

In response to this argument, it is repeated again that the reference teaches application across the chest which is from one side to the other of the chest or around the chest, and in any case the cooling strip will possibly applied to the back or across the chest all around to encompass the back. Patterson does not teach away from application on the back, and Patterson achieved treatment of hot flashes by application of the cooling strip across the chest. It has been held that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551,553 (Fed. Cir. 1994). Patterson does not teach away from treating hot flashes by applying cooling strips to the invisible part of the woman body such as across the chest that suggested the back of the chest as well as front of the chest.

Applicant argues JP '529 and US '899 do not disclose, teach or suggest any methods for treating hot flashes associated with menopause in a woman including providing a woman experiencing a hot flash with a cooling device in a package having instructions to place a cooling device on a skin region at a location on her upper back, which location is a site of origin of the hot flash, to thereby treat the hot flash. Both JP

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'529 and U.S. '899 are deficient with regard to the present claims, and do not supply the deficiencies apparent in Patterson.

In response to this argument, it is argued that treating hot flashes using cooling strips is taught by Patterson, and further Patterson teaches application of the cooling strips across the chest. Regarding the site of origin of hot flashes can be in the back, this is taught by Kronenberg. JP '529 and US '899 are relied upon for the sole teaching of making the strip of hydrous material comprising polyacrylic acid. One would have been motivated to use polyacrylic acid for making the cooling strip because JP '529 teaches that such a cooling patch can be applied to the affected area that in need of cooling and hydrous polyacrylic acid can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay. Further, one would have been motivated to use polyacrylic acid for making the cooling strip because US '899 teaches that cooling sheet can be applied locally to the area of discomfort and polyacrylic acid cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue. One would have reasonably expected treating hot flashes using cooling strip or sheet applied across the chest comprising polyacrylic acid gelatinous material located between skin adhesive and cotton fabric layer wherein the strip or sheet is applied at the site of origin of the discomfort, in this case is the hot flash, and is able to maintain the cooling effect and preserve the coolness to treat hot flashes successfully and effectively.

Applicant argues that Kronenberg does not disclose, teach or suggest any methods for treating hot flashes associated with menopause in a woman comprising providing a woman experiencing a hot flash with a cooling device in a package having instructions to place the cooling device on a skin region at a location on her upper back, which location is the site of origin of the hot flash, or placing a cooling device on a skin region at a location on the upper back of the woman which location is a site of origin of the hot flash, as recited in the present claims. Kronenberg does not mention or even suggest the back of the woman which is a site of origin of the hot flash.

In response to this argument, it is argued that treating hot flashes using cooling strips is taught by Patterson, and further Patterson teaches application of the cooling strips across the chest. Kronenberg is relied upon for the solely teaching of the onset of the hot flashes and sweating occur primarily on the chest and upper torso, i.e. trunk. The trunk includes both front and back of the torso. One having ordinary skill in the art at the time of the invention would have been motivated to apply the cooling sheet taught by the combination of US '904 with any of JP '529 or US '899 to the trunk of the woman including back of the women as disclosed by Kroneberg et al. One would have been motivated to do so because Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso. One would have reasonably expected treating hot flashes by applying cooling sheet to the upper back which is the primary site of onset of the hot flashes.

Applicants argues that Patterson alone or in combination with one or more of the other references relied on by the Examiner does not disclose, teach or even suggest the present claims and the surprising, unexpected and unpredictable combination of advantages achieved by applicant in accordance with the present claims.

In response to this argument, it is argued that the invention as a whole is suggested and taught by the combination of the cited prior art and the invention as a whole would have been prima facie obvious in the meaning of USC 103 (a). In addition, regarding applicant's arguments of unexpected superior results in the instant specification, it is the examiner's position that the data in the specification regarding application to the upper back are not unexpected results and therefore can not rebut prima facie obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

Applicant argues that the prior art provides no motivation or incentive, no other reasonable or rational basis and no common sense basis for one of ordinary skill in the art to combine, modify and extend the deficient teachings of the prior art to make

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obvious the present claims and obtain the surprising, unexpected and unpredictable combination of advantages of such claims achieved by applicant.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling sheet/strip applied across the chest to treat hot flashes comprising gelatinous material located between skin adhesive and cotton fabric layer as taught by US '904, and apply the strip to the origin of the hot flashes and make the strip of hydrous material comprising polyacrylic acid as taught by any of JP '529 and US '899. One would have been motivated to do so because JP '529 teaches that such a cooling patch can be applied to the affected area that in need of cooling and hydrous polyacrylic acid can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay. Further, one would have been motivated to do so because US '899 teaches that cooling sheet can be applied locally to the area of discomfort and polyacrylic acid cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue. One would have reasonably expected treating hot flashes using cooling strip or sheet applied across the chest comprising polyacrylic

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acid gelatinous material located between skin adhesive and cotton fabric layer wherein the strip or sheet is applied at the site of origin of the discomfort, in this case is the hot flash, and is able to maintain the cooling effect and preserve the coolness to treat hot flashes successfully and effectively. Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to apply the cooling sheet taught by the combination of US '904 with any of JP '529 or US '899 to the back of the women as taught by Kroneberg et al. One would have been motivated to do so because Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso. One would have reasonably expected treating hot flashes by applying cooling sheet to the upper back which is the primary site of onset of the hot flashes.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed

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by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even attempt to practice the present claims. None of the prior art even suggests placing a cooling device on a skin region at a location on the upper back of a woman experiencing a hot flash which location is a site of origin of the hot flash, as in the present claims.

In response to applicant's argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of

ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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